

SIDLEY AUSTIN BROWN & WOOD LLP

BEIJING
BRUSSELS
CHICAGO
DALLAS
GENEVA
HONG KONG
LONDON

555 WEST FIFTH STREET
LOS ANGELES, CALIFORNIA 90013
TELEPHONE 213 896 6000
FACSIMILE 213 896 6600
www.sidley.com
FOUNDED 1866

LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
TOKYO
WASHINGTON, D.C.

FACSIMILE/TELECOPIER TRANSMISSION

From: Name: Carissa Tener (213) 896-6621
Voice: Rosalyn Jones (213) 896-6841

To: Name: Alton N. Pryor, Examiner, Group Art Unit 1616
Company:
Facsimile#: 703-872-9306
Voice Phone:
Subject: Pulmonox

RECEIVED
CENTRAL FAX CENTER

AUG 08 2005

Date: 08/08/2005 Time: 04:04:45 PM No. Pages (Including Cover): 16

Message:

U.S. Patent Application For: EXOGENENOUS NITRIC OXIDE GAS (gNO) THERAPY IN WOUND HEALING
Serial No.: 10/615,546
Previous Docket No.: 0-03-046
Our Docket No.: 24647-81101

Examiner Pryor:

Attached please find a courtesy copy of Applicants' Response and Amendment to the Office Action mailed

* * * * *

To ensure our compliance with certain Internal Revenue Service regulations, we inform you that, unless expressly stated otherwise, any advice in this facsimile relating to U.S. federal taxes is not intended or written to be used, and cannot be used, by any person for the purpose of avoiding any tax penalties that may be imposed by the Internal Revenue Service.

* * * * *

Problems with this transmission should be reported to:

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL(S) OR ENTITY(IES) TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR DELIVERING THE MESSAGE TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE.

SIDLEY AUSTIN BROWN & WOOD LLP IS A LIMITED LIABILITY PARTNERSHIP
PRACTICING IN AFFILIATION WITH OTHER SIDLEY AUSTIN BROWN & WOOD PARTNERSHIPS

SIDLEY AUSTIN BROWN & WOOD LLP

BEIJING
BRUSSELS
CHICAGO
DALLAS
GENEVA
HONG KONG
LONDON

555 WEST FIFTH STREET
LOS ANGELES, CALIFORNIA 90013
TELEPHONE 213 896 6000
FACSIMILE 213 896 6600
www.sidley.com
FOUNDED 1866

LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
TOKYO
WASHINGTON, D.C.

March 10, 2005. I would like to thank you for discussing possible amendments to the claims with me back in June. As you will see, Applicants' have made several amendments to the claims as we've discussed.

Thank you.

Carissa A. Tener
Reg. No.: 52,278

* * * * *

To ensure our compliance with certain Internal Revenue Service regulations, we inform you that, unless expressly stated otherwise, any advice in this facsimile relating to U.S. federal taxes is not intended or written to be used, and cannot be used, by any person for the purpose of avoiding any tax penalties that may be imposed by the Internal Revenue Service.

* * * * *

Problems with this transmission should be reported to:

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL(S) OR ENTITY(IES) TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR DELIVERING THE MESSAGE TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE.

SIDLEY AUSTIN BROWN & WOOD LLP IS A LIMITED LIABILITY PARTNERSHIP
PRACTICING IN AFFILIATION WITH OTHER SIDLEY AUSTIN BROWN & WOOD PARTNERSHIPS

Office Action Summary

Application No.

10/615,548

Applicant(s)

MILLER ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 9-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 9-15, 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Application/Control Number: 10/615,546

Page 2

Art Unit: 1616

DETAILED ACTION

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-15, 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenzler on record. Stenzler teaches a method of promoting healing of a wound comprising topically applying to the damaged tissue (wound) which is surrounded by an air impermeable cover (bathing unit) an effective amount of gaseous nitric oxide (wound healing agent), oxygen (wound healing agent) and nitrogen (inert agent that enhances local amount nitric oxide delivered to wound). The nitric oxide is applied from a pressurized cylinder which suggests a spray application method. Stenzler teaches that nitrogen prevents the nitric oxide from converting to NO₂. See abstract, column 4 lines 1-47. The method promotes the healing of infections incurred by bacteria (pathological process). See column 3 lines 17-25. Stenzler employs a nitric oxide concentration ranging from about 100 to around 1200 ppm in the method. See column 3 line 46 – column 4 line 24. Stenzler teaches the exposure of wound to nitric oxide for an average of 8 hours. See column 2 lines 7-22. Stenzler does not teach a method employing 20-1000 ppm gaseous nitric acid. Stenzler's method does disclose a step wherein the

Application/Control Number: 10/615,546

Page 3

Art Unit: 1616

wound is pretreated or posttreated with nitric oxide plus an agent. In essence both Applicant and Stenzler teaches a step involving topically applying gaseous nitric oxide plus an agent to a wound. Stenzler teaches that the application of gaseous nitric oxide plus agent is prior to or after exposing the wound to nitric oxide. However, in the absence of unexpected results, it is obvious that both inventions would yield similar results since both prior art and instant inventions teach the step of applying gaseous nitric oxide plus an agent to the wound. It would have been obvious to one having ordinary skill in the art to employ the instant ppm amount of gaseous nitric acid since the prior art and instant invention ppm amounts of gaseous nitric overlap.

Claims 9-15, 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hole on record. Hole teaches a method of promoting healing of a wound comprising topically applying to the damaged tissue (wound) which is surrounded by an air impermeable cover (envelope) an effective amount of gaseous nitric oxide (wound healing agent), oxygen (wound healing agent) and nitrogen (inert agent that enhances local amount nitric oxide delivered to wound). The nitric oxide is applied from a pressurized cylinder which suggests a spray application method. Hole teaches that nitrogen prevents the nitric oxide from converting to NO₂. See abstract, paragraph 36. The method promotes the healing of infections incurred by bacteria (pathological process). See paragraph 9. Hole employs a nitric oxide concentration ranging from about 100 to around 1000 ppm in the method. See paragraphs 42-43. Hole teaches the exposure of wound to nitric oxide for an average of 8 hours. See paragraph 10. Hole does not teach a method employing 20-1000 ppm gaseous nitric acid. Hole's method

Application/Control Number: 10/615,546
Art Unit: 1616

Page 4

does disclose a step wherein the wound is pretreated or posttreated with nitric oxide plus a wound healing agent. In essence both Applicant and Hole teaches a step involving topically applying gaseous nitric oxide plus an agent to a wound. Hole teaches that the application of gaseous nitric oxide plus agent is prior to or after exposing the wound to gaseous nitric oxide. However, in the absence of unexpected results, it is obvious that both inventions would yield similar results since both prior art and instant inventions teach the step of applying gaseous nitric oxide plus an agent to the wound. It would have been obvious to one having ordinary skill in the art to employ the instant ppm amount of gaseous nitric acid since the prior art and instant invention ppm amounts of gaseous nitric overlap.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.